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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/643,260	08/22/2000	Michael J. May	PPI-117	9021

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EXAMINER
MITRA, RITA

ART UNIT	PAPER NUMBER
1653	9

DATE MAILED: 09/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

Office Action Summary	Application No.	Applicant(s)	
	09/643,260	MAY ET AL.	
	Examiner	Art Unit	
	Rita Mitra	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the c rrespondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 July 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *1-18 and 23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 August 2000* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restriction

Applicants' election with traverse of Group VII (claims 19, 20, 21 and 22) and SEQ ID NO: 6 in paper #8 (filed on July 16, 2002) is acknowledged. The traversal is on the ground that Group VI and Group VII should be regrouped as a single invention, as Groups VI and VII encompass inventions, which are connected in design, operation and effect, i.e., are not independent (M.P.E.P. 808.01). Specifically, the invention of Group VI is directed to fusions of the polypeptides of Group VII. In addition Applicants urge that as such, a search of the fusion peptides of claim 15 (Group VI) would necessarily uncover art pertaining to the polypeptides of claim 19 (Group VII) because the fusion peptide of claim 15 encompass the polypeptide of claim 19. Therefore, Applicants submit that a sufficient search and examination with respect to the inventions of Groups VI and VII can be made without serious burden on the Examiner. The traversal has been fully considered and not found persuasive because Groups VI and VII are directed to different subject matter, as the claim 19 of Group VII does not recite or indicate the fusions of the polypeptides that directs to the invention of Group VI, neither the claim 19 is depending on claim 15 of Group VI. Therefore, the inventions of Group VI and Group VII are not connected in design, operation and effect and they are independent.

The restriction requirement is still deemed proper and is therefore made **FINAL.**

Claims 1-18 and 23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected invention. Therefore, claims 19-22 are currently pending and are under examination.

Priority

Applicant's claim for domestic priority under 35 U.S.C. 119 (e) is acknowledged. This application claims a priority of Application No. 60/201,261, filed on May 2, 2000. This Application fails to provide the sequences claimed in a printed or computer readable form. Therefore, the priority date granted is August 22, 2000, which is a filing date of this application.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated peptide comprising an amino acid sequence set forth in SEQ ID NO: 6; does not reasonably provide enablement for all mutants or fragments generated from any position located on the sequence of SEQ ID NO: 6. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claims 19-22 encompass an isolated peptide comprising an amino acid sequence set forth in SEQ ID NO: 6 and the fragments, mutants and variants thereof (claim 19), a composition comprising the said peptides (claim 20) and a carrier (claim 21), an isolated peptide consisting of the amino acid sequence of SEQ ID NO: 6 (claim 22). The specification, however, only discloses cursory conclusions (see page 13-15), without data to support the findings, which state that the molecules that down-regulate interaction of NEMO with the IKK complex is part of the invention. The specification further indicates at page 14 that binding agents specific to NEMO, capable of blocking interaction of NEMO at the nemo-binding domain (NBD) on IKKβ. Exemplary IKKβ inhibitors include competitive inhibitors of NEMO binding at the NBD, for example, the peptide set forth in SEQ ID NO: 2 and conservative substitution thereof, which has no significant effect on NEMO binding at NBD (Table 1). There are no indicia that the present application enables the full scope in view of the peptides of SEQ ID NO: 1 and a mutant thereof as discussed in the following stated rejection. The present application provides no indicia and no teaching/guidance as to how the full scope of the claims is encompassed.

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation. The factors include: 1) the nature of the invention; 2) the breadth of the claims; 3) the predictability or unpredictability of the art; 4) the amount of direction or guidance presented; 5) the presence or absence of working examples; 6) the quantity of experimentation necessary; 7) the state of the prior art; and, 8) the relative skill of those skilled in the art;

Each factor is addressed below on the basis of comparison of the disclosure, the claims and the state of the prior art in the assessment of undue experimentation.

1) the nature of the invention:

The nature of the invention is defined by the claims, which include an isolated peptide having an amino acid sequence set forth in SEQ ID NO: 1 and a fragment/mutant/variant thereof. However the specification does not provide the information on the structure and function of the claimed mutants.

2) the breadth of the claims:

The breadth of the claims is broad and encompasses an unspecified amount of variants regarding the peptide products of SEQ ID NO: 6 as biological active fragments, which are not specifically described or demonstrated in the specification.

Claim 19 is drawn to an isolated peptide comprising an amino acid sequence set forth in SEQ ID NO: 6 and the fragments, mutants and variants thereof which has a property of inhibiting the interaction of NEMO with IKKβ at the NBD. The specification indicates at page 15 lines 1-4 that conservative substitutions of amino acid residues of the peptide set forth in SEQ ID NO: 2 at positions 737, 740 and 742 are also encompassed in the invention (Table 1). Table I indicates the peptide of SEQ ID NO: 6 has ability to bind to NEMO, however specification fails to provide any description of the fragments or mutants or naturally occurring amino acid sequence variants of peptide sequence of SEQ ID NO: 6 or a composition comprising the said variants. For these reasons, it requires undue experimentation to make the claimed invention,

especially where in claim 19, any one or more amino acid residues, singly or in any combination of substitution would have been included by the claim and for which the specification does not describe with particularity as to the function of binding to NEMO.

3) the predictability or unpredictability of the art:

The invention is highly unpredictable for the reasons set forth for factors 1 and 2 above.

4) the amount of direction or guidance presented;

5) the presence or absence of working examples; and,

6) the quantity of experimentation necessary:

The claims are directed to an isolated peptide comprising amino acid sequence set forth in SEQ ID NO: 6 and a fragment/mutant/variant thereof. However, the specification provides only a generic description of how a variety of mutants can be generated (page 11-12), no specific guidance is provided on the generation of the mutants or fragments or variants that demonstrate the biological activity of the peptide sequence of SEQ ID NO: 6. There are no working examples of these variants in the specification. While the specification in Example 4, page 44-45 and in Table 1 describes and demonstrates that the peptide set forth in SEQ ID NO: 6 is asserted to bind with NEMO, there is no disclosure about the biological activities of the claimed variants generated from peptide of SEQ ID NO: 6. Since the specification fails to provide sufficient guidance on the structure and function of the various mutants, fragments and variants, it is necessary to have additional guidance on the identities of those variants to carry out further experimentation to assess their property of interacting with NEMO.

7) the state of the prior art; and,

8) the relative skill of those skilled in the art:

The prior art has shown a cell-permeable NBD peptide that blocks association of NEMO with the IKK complex and inhibited cytokine-induced NF-kB activation and NF-kB dependent gene expression (see May et al., Science, vol 289, September 1, 2000; IDS ref. A18), however, the general knowledge and level of the skill in the art do not supplement the omitted description,

the specification needs to provide specific guidance on the structure and function for various protein products to be considered enabling for variants.

In consideration of each of factors 1-8, it is apparent that undue experimentation is required because in summary, the scope of the claim is broad, the working example does not demonstrate the claimed variants, the guidance/the teaching in the specification is limited, and the outcome is unpredictable for the various modified forms, it is necessary to have additional guidance and to carry out further experimentation to assess the property of the variants. Therefore, due to large quantity of experimentation necessary to determine an activity or property of the disclosed peptide and the modified forms thereof, such that it can be determined how to use the claimed peptides, the lack of direction/guidance presented in the specification regarding same, the absence of working examples directed to same, the complex nature of the invention, the specification fails to teach the skilled artisan how to make and use the claimed invention.

Claim Rejections-35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 19-22 are rejected under 35 U.S.C. 102(a) as anticipated by Bower et al. (WO 99/31255, June 24, 1999). Bower et al. teach an EGIII-like cellulase of Gliocladium roseum, which has 92.5% sequence identity to SEQ ID NO: 6 (see sequence alignment result, A_Geneseq_032802 database, Accession NO: AAY06332, September 6, 1999). This reads on claims 19, 20 and 21, which has any size of fragment, any number of substitutions both singly and/or in any combination (claim 19, 22). See the sequence alignment attached to the Bower et al. reference. As to claims 20 and 21, the Bower et al. reference discloses a composition

comprising the cellulase (page 21, lines 6-8) that would have been the composition that contains the peptide of claim 19.

Conclusion

No claims are allowed.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rita Mitra whose telephone number is (703) 605-1211. The Examiner can normally be reached from 9:30 a.m. to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Christopher Low, can be reached at (703) 308-2923. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen Cochrane Carlson PhD

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER

R Mitra

Rita Mitra, Ph.D.
September 18, 2002